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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Morten Reeslev

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EXAMINER

MARTIN, PAUL C

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,321	Applicant(s) REESLEV ET AL.	
	Examiner PAUL C. MARTIN	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 46 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-45 is/are rejected.
- 7) ☒ Claim(s) 19 and 48-51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-51 are pending in this application.

This application contains claims 46-47 drawn to an invention nonelected with traverse in the reply filed on 08/14/2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-45 and 48-51 were examined on their merits.

The objection to the Specification for improper citation of Trademarks has been withdrawn due to the Applicant's amendments to the Specification filed 02/17/09.

The objection to Claim 3 for minor spelling informalities has been withdrawn due to the Applicant's amendments to the Claims filed 02/17/09.

The rejection of Claims 1-45 under 35 U.S.C. § 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention has been withdrawn due to the Applicant's amendments to the Claims filed 02/17/09.

The rejection of Claim 17 under 35 U.S.C. § 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as

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the invention has been withdrawn due to the Applicant's amendments to the Claims filed 02/17/09.

The rejection of Claim 19 under 35 U.S.C. § 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention has been withdrawn due to the Applicant's amendments to the Claims filed 02/17/09.

The rejection of Claims 1, 3, 4, 6, 7, 10, 11, 14-17, 20, 22-25, 28, 35 and 36 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ralls *et al.* (US 5,741,659) has been withdrawn due to the Applicant's arguments regarding the invention being found to be persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-4, 6, 7, 10-13, 16, 17, 20, 22-28, 35, 36 and 40-45 remain rejected under 35 U.S.C. 102(b) as being anticipated by Tuompo *et al.* (US 5,714,343) for reasons of record set forth in the Prior Action.

Claims 1, 3, 4, 6, 7, 10, 11, 14, 15, 17, 20, 22-25, 27, 28, 31, 32, 33, 35 and 36 remain rejected under 35 U.S.C. 102(b) as being anticipated by Laine *et al.* (US 6,090,573) for reasons of record set forth in the Prior Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 10-13, 16, 17, 20, 22-30, 35, 36 and 40-45 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Tuompo *et al.* (US 5,714,343) for reasons of record set forth in the Prior Action.

Claims 1-7, 10-13, 16, 17, 18, 20, 22-30, 35, 36, 37, 38 and 40-45 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Tuompo *et al.* (US 5,714,343) in view of Koumura *et al.* (US 4,591,554) for reasons of record set forth in the Prior Action.

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Claims 1, 3, 4, 6, 7-11, 14, 15, 17, 20-25, 27, 28, 31-36 and 39 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Laine *et al.* (US 6,090,573) for reasons of record set forth in the Prior Action.

Response to Arguments

Applicant's arguments, see Remarks, Pg. 19-20, filed 02/17/09, with respect to the rejection of Claims 1, 3, 4, 6, 7, 10, 11, 14-17, 20, 22-25, 28, 35 and 36 under 35 U.S.C. § 102(b) have been fully considered and are persuasive. The rejection has been withdrawn.

Applicant's arguments filed 02/17/09 have been fully considered but they are not persuasive.

Applicant argues that the Tuompo *et al.* reference does not anticipate the instant invention because Tuompo *et al.* requires the detection of the microorganisms to be done on the filter, and points to two citations in the reference wherein the filter is monitored for color formation and that Tuompo *et al.* teaches away from the use of the soluble substrate MTT and that using soluble chromogenic agents such as MTT would render the invention inoperable (Remarks, Pg. 18, Lines 8-14 and Pg. 22, Lines 4-14 and Pg. 23, Lines 5-14).

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This is not found to be persuasive for the following reasons, while Tuompo *et al.* certainly indicate that the preferred embodiment is passing the dye NBT over filter immobilized microorganisms such that the microorganisms on the filter are visible, the reference further teaches that the soluble dye MTT is useful as an alternative and would pass through the filter to be visualized via spectrophotometry. This would meet the limitations of claim 1.

Applicant argues that Tuompo *et al.* distinguishes his invention and the use of MTT, and teaches against the use of MTT in the assay as it does not adhere to the filter and cannot be detected without separate measuring equipment, such as spectrophotometry. The Applicant states that there is no teaching in the reference of any spectrophotometric method that utilizes a filter and alleges that the reference only discusses the use of MTT in prior art histology slide or solution based methods to detect living bacteria by observable color change in response to contact with MTT (Remarks, Pg. 18, Lines 15-26 and Pg. 19, Lines 1-3).

This is not found to be persuasive for the following reasons, while the reference does not teach the use of MTT in its preferred embodiment the reference is still nonetheless valid for that teaching. While the preferred embodiment may not require a spectrophotometer, the reference recognizes that when using a soluble substrate such as MTT, further detection means may be required.

Applicants assertion that MTT is only taught with regard to histology or solution based methods is not found persuasive in view of the totality of the teachings of the reference, that is the use of enzyme substrates to contact filter entrapped microorganisms and detect them via

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color formation using either dyes which precipitate out onto the filter or alternatively dyes which are soluble and are detected via spectrophotometer. The MPEP states:

“The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain.” *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)).

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989).

“Arguments that the alleged anticipatory prior art is nonanalogous art’ or teaches away from the invention’ or is not recognized as solving the problem solved by the claimed invention, [are] not germane’ to a rejection under section 102.” *Twin Disc, Inc. v. United States*, 231 USPQ 417, 424 (Cl. Ct. 1986) (quoting *In re Self*, 671 F.2d 1344, 213 USPQ 1, 7 (CCPA 1982))

A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. The question whether a reference “teaches away” from the invention is inapplicable to an anticipation analysis. *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998).

Applicant argues that Laine *et al.* does not teach a detectable moiety produced through interaction of a substrate with contaminants, rather the reference teaches the binding of an enzyme conjugate to the sample components and then a secondary substrate is added to form a colored precipitate upon cleavage by the bound conjugate. Applicant states that therefore the

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reference teaches an interaction producing a detectable moiety is between an exogenous enzyme conjugate and an exogenous enzyme substrate and not between the contaminants and a substrate (Remarks, Pg. 20, Lines 22-23 and Pg. 21, Lines 1-12 and Pg. 24, Lines 4-11).

This is not found to be persuasive for the following reasons, the instant claim 1 contains comprising language and states, "...contacting the influent side of the filter in the filter device with a liquid vehicle containing at least one substrate, said at least one substrate being one which through interaction with the contaminants produces a detectable moiety..." The method of Laine *et al.* teaches a two part detection system comprising labeling contaminants (bacteria, fungi and or cell wall degradative products trapped on the filter) with a detect reagent such as lysozyme-alkaline phosphatase conjugate and then contacting the bound conjugate with alkaline phosphatase substrate and detecting/quantifying the color reaction in the eluent. The Applicant's open language in no way precludes a multi-component linked enzyme assay system, and the binding and labeling with conjugate and detection with substrate certainly qualifies as an interaction between the contaminants and at least one substrate even if indirectly.

The Applicant argues that Laine *et al.* teaches introducing the alkaline phosphatase substrate in a diethanolamine/MgCl vehicle, and the use of an 80% ethanol solution to elute the blue alkaline phosphatase product from the filter as opposed to instant claim 1 which requires that the detectable moiety that is detected "in the liquid vehicle". The Applicant states that the "liquid vehicle" is the vehicle in which the substrate was introduced and therefore Laine *et al.*

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teaches elution and detection with a vehicle separate from the vehicle in which the substrate is introduced (Remarks, Pg. 21, Lines 13-20 and Pg. 24, Lines 4-11).

This is not found to be persuasive for the following reasons as discussed above, the open language of the claim do not preclude a multicomponent system wherein the first conjugate component is delivered in a TBS liquid medium and the second component being delivered in a second diethanolamine/MgCl vehicle. The two vehicles combining to form one liquid vehicle in which the detectable moiety is detected. Laine *et al.* only requires elution for *quantification* of the colored substrate, but clearly color appears and is detectable prior to said elution step in the combined liquid medium vehicle meeting the claim limitations.

Conclusion

No Claims are allowed. Claims 19 and 48-51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL C. MARTIN whose telephone number is (571)272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

03/30/09

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657